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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 09/653,794 Confirmation No. 5973
 Applicant : Meir S. Sacks et al.
 Filed : September 1, 2000
 Title : COMPOSITIONS AND METHODS FOR TREATING
 SEXUAL DYSFUNCTION
 TC/A.U. : 1615
 Examiner : Gollamudi S. Kishore
 Docket No. : 286262-00005
 Customer No. : 29694

AUG 04 2004

DECLARATION UNDER 37 CFR 1.132

(CENTER 1600/2900)

I, Meir S. Sacks, do hereby declare that:

(1) I received a Bachelor of Science degree in Biology from Duquesne University in 1991, a Masters of Science degree in Microbiology from Duquesne University in 1994, and a Ph.D. degree from West Virginia University in 1998. Since 1998, I have worked in the field of biochemistry and have authored several publications in that field. I am currently Director of Technology Evaluation for Licensing and Acquisition of Arkios BioDevelopment International.

(2) I am a named inventor in the above-referenced application.

(3) I am familiar with the prosecution of this application. During prosecution, independent Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,207,713 to Fossel or U.S. Patent No. 6,476,037 to Wallace in view of U.S. Patent No. 6,139,847 to Chobanian et al. Independent Claim 13 was further rejected under 35 U.S.C. § 103(a) as being unpatentable over the Fossel '713, Wallace '037 and Chobanian et al. '847 patents in view of U.S. Patent No. 6,007,824 to Duckett et al. by itself or in further combination with U.S. Patent No. 6,031,002 to Wysor.

(4) The presence of esterified L-arginine comprising ethyl ester of L-arginine in the composition recited in this application significantly and unexpectedly improves sexual response in women who topically apply the composition. I conducted a study to demonstrate these facts. The study described below was conducted by me.

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(5) Five women, each with various sexual dysfunctions, comprised the test group. Their dysfunctions ranged from the inability to produce any vaginal moisture (this woman having had laproscopic removal of the ovaries approximately three years prior to testing) to women with varying degrees of lack of orgasmic fulfillment. Results were graded on a 0 to 10 basis, as reported by the women, with 0 being no sexual response at all to 10 being an extremely powerful sexual response. Each woman was given compositions including: (1) a control (which was a PLO vehicle with no active ingredient); (2) a composition comprising the PLO vehicle with L-arginine and antioxidant (comprising a combination of ascorbic acid and ascorbic acid-6-palmitate in a 1:1 ratio); and (3) a composition comprising the PLO vehicle with esterified L-arginine (comprising the ethyl ester of L-arginine or a combination of the ethyl ester and the methyl ester of L-arginine) and antioxidant (comprising a combination of ascorbic acid and ascorbic acid-6 palmitate in a 1:1 ratio). The ratio of L-arginine or esterified L-arginine to antioxidant in compositions (2) and (3) was approximately 2:1. The compositions were formulated according to methods commonly known to those skilled in the art for formulating liposomal solutions.

(6) In a round of testing, the concentrations of L-arginine in composition (2) and L-arginine ethyl ester in composition (3) were approximately 25 milligrams. In response to the use of composition (3) containing the ethyl ester of L-arginine of the presently claimed invention, four of the five women reported increases in their sexual experience. The first woman, who was originally a 6, reported a response of almost 10 by using composition (3) containing the L-arginine ethyl ester. The woman with the inability to autolubricate went from 0 to a 10 in response to the L-arginine ethyl ester composition (3). The third woman went from a 2 to about a 6 based upon using the L-arginine ethyl ester composition (3). The fourth woman, who had previously rated her sexual experience at about 1, rated her experience, based upon using the L-arginine ethyl ester composition (3), at a 3. The fifth woman reported no significant differences between any of the categories.

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(7) None of the women reported a response to the control composition (1) or the L-arginine composition (2). When an enhanced sexual response was realized, it occurred with composition (3) comprising the esterified L-arginine. The results of the study are shown in the following table.

Sexual Response Score
(Scale of 1 to 10)

Subject No.	Baseline (No Treatment)	Composition 1 Control (Vehicle Alone)	Composition 2 Vehicle Plus L-Arginine and Antioxidant	Composition 3 Vehicle Plus Ethyl Ester of L-Arginine and Antioxidant
1	6	6	6	10
2	0	0	0	10
3	2	2	2	6
4	1	1	1	3
5	*	*	*	*

* Subject reported essentially no difference between categories.

(8) This study demonstrates that the composition of the presently claimed invention comprising the ethyl ester of L-arginine produced unexpectedly improved results in comparison with both the composition comprising no active ingredient and the composition comprising L-arginine.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Date: July 28, 2004


Meir S. Sachs